K092375

510(k) SUMMARY

SEP - 4 2009

SI-Bone's SI Fusion System

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Hogan & Hartson LLP
555 13th St., NW
Washington, DC 20004

Phone: (202) 637-5813
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Contact Person: Howard M. Holstein

Date Prepared: July 31, 2009

Name of Device and Name/Address of Sponsor

SI Joint Fusion System

SI-Bone, Inc.
20045 Stevens Creek Blvd. Suite 1F
Cupertino, CA 95014

Common or Usual Name: Orthopedic Rods

Classification Name: 21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener

Predicate Devices

SI-Bone, Inc's SI Joint Fusion System

Purpose of the Special 510(k) notice.

The SI Joint Fusion System is a modification to SI-Bone's cleared SI Joint Fusion System.

Intended Use

The SI Joint Fusion System is intended for fracture fixation of large bones and large bone fragments of the pelvis for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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Technological Characteristics

The SI Fusion System consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create fixation. The system includes 4.0 mm and 7.0 mm diameter fusion rods, which range in length from 30 mm to 70 mm.

Performance Data

A Finite Element Analysis (FEA) was performed on the SI Fusion System in comparison to its predicate. Results demonstrate that the SI Fusion System is substantially equivalent with respect to fixation of the SI joint.

Substantial Equivalence

The SI Joint Fusion System has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate SI Joint Fusion System. The minor differences in the SI Joint Fusion System's technological characteristics, namely the inclusion of 4.0 mm diameter rods in the system, do not raise any new questions of safety or effectiveness. Performance data demonstrates that the SI Joint Fusion System is as safe and effective as previously cleared SI Joint Fusion System. Thus, the SI Joint Fusion System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SI-Bone, Inc.
% Hogan & Hartson LLP
Mr. Howard M. Holstein
Hogan & Hartson LLP
555 13th Street North West
Washington, District of Columbia 20004

APR - 7 2011

Re: K092375
Trade/Device Name: SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fastener
Regulatory Class: II
Product Code: OUR
Dated: August 3, 2009
Received: August 5, 2009

Dear Mr. Holstein:

This letter corrects our substantially equivalent letter of September 04, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

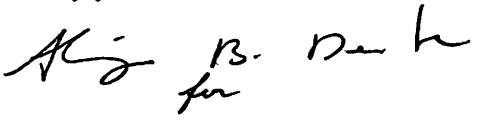
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092375

Device Name:

Indications for Use:

The SI-Bone SI Joint Fusion System is intended for fracture fixation of large bones and large bone fragments of the pelvis for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092375